IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: CAROL CARTER, ET AL.	)	Confirmation No: 6642
	)	
Application No.: 10/666,997	)	Group Art Unit: 1648
	)	
Filed: SEPTEMBER 18, 2003	)	Examiner: HUMPHREY, LOUISE

For: TSG101 AS INHIBITOR OF HIV PRODUCTION

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APPEALLANT'S REPLY BRIEF

Sir:

This is in response to the Examiner's Answer mailed February 22, 2010. In replying herein, Appellants expressly carry forward the arguments advanced in their Brief on Appeal, and incorporate them herein. For the sake of brevity, they are not repeated. Rather, this Reply focuses on arguments advanced in the Examiner's Answer that are respectfully submitted to be inconsistent with the record, or inconsistent with the law.

THE SOLE REJECTION IS FOR LACK OF ENABLEMENT

Claims 93, 94 and 132-134 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement.

As happens all too often in prosecution before the Board, the Examiner's Answer of February 22, 2010 talks right past Appellants' Brief on Appeal, without offering any observations as to why the arguments advanced in that Brief are wrong or insufficient. In this Reply Brief, Appellants respond to what are essentially two positions advanced by the Examiner, relying on the record developed in prosecution, in this case and in the parent application which is now U.S. Patent No. 7,494,767, to demonstrate that it is the Examiner's position that is inconsistent with the prosecution to date, and the law.

The Examiner's rejection is grounded first on the argument that an insufficient number of peptides for use in connection with this invention are disclosed to enable it. The Examiner argues "[T]here is no *in vitro* or *in vivo* working example that shows the effectiveness of an PTAP-containing peptides in inhibiting particle formation." See, Answer, p.4. As shown below, Applicants have already demonstrated that the specification presented is enabling for identification of all such peptides. The Examiner also argues that the disclosure is not sufficient to enable the treatment of HIV infection "without sufficient guidance to the safety, bioavailability, plasma concentration, and antiviral effect" of the claimed invention. See, Answer, page 7. As discussed below, Applicants are not claiming treatment of HIV, and the Office has already agreed that this is patentably distinct from what Applicants ARE claiming.

I. THE SPECIFICATION IS ENABLING FOR ALL PTAP CONTAINING PEPTIDES CALLED FOR

As noted, the claims call for the administration of a "peptide comprising a PTAP motif that inhibits binding between TSG101 protein and HIV gag polypeptide and thereby inhibits HIV particle generation." See, Claim 93. The Examiner's Answer seems to suggest that without multiple examples of such peptides, such a claim cannot be enabled. In this, the Examiner errs.

The legal issue is framed not by whether the specification provides multiple working examples of the peptide employed by the claims on appeal, it turns solely on whether the specification enables the artisan to identify such peptides. Indeed, no listing of suitable peptides could possibly be as complete as an assay which teaches the artisan how to find all such peptides. The Examiner has already concluded that in fact the specification of the application on appeal, as originally filed, contains such an assay. On November 25, 2008, in the prosecution of this application, the Examiner acknowledged:

> The instant specification discloses…an assay for identifying all PTAP-containing peptides that are effective at inhibiting the binding between Tsg101 and the HIV Gag protein and thereby blocking the HIV particle generation step in the virus lift cycle.

Office Action of November 25, 2008 at page 9.

This was noted in the Appeal Brief the Examiner's "Answer" is responsive to at page 14 of that Brief. The Examiner's Answer makes no mention of it. This was not some casual statement, or a misquotation. The next office action, rejection of May 11, 2009 acknowledges this to be the case – page 10. Respectfully, given the disclosure of an assay that allows one to identify all PTAP-comprising peptides satisfying the claims, the fact that the specification

identifies only a couple, and demonstrates that they do in fact inhibit particle release, is not a basis for rejection for lack of enablement.

II. THERE IS NO CLAIM DIRECTED TO INTI-VIRAL TREAMTENT

Much of the Examiners rejection dwells on the lack of disclosure in the specification of an embodiment that will be an effective anti-viral treatment, *in vivo*, in humans. Issues such as those discussed in the paragraph bridging pages 5–6 of the Examiner's Answer, including "understanding the molecular determinants modulating many viral protein and those cell factor interactions" and "failure of *in vitro* tissue culture studies and *in vivo* models to adequately predict clinical efficiency" as well as "the failure of many compounds to have acceptable pharmacological profiles" and the "failure of related structural analogs to function in the desired manner" are all issues one must consider in delivering an anti-viral treatment for use in humans. Applicants are not claiming that. The claims are indifferent to that.

Applicants have demonstrated that in fact the claimed method is effective in inhibiting viral propagation. That's important. It may be a critical step in fashioning a new way of treating diseases such as AIDS. Whether it is or is not such a critical step – it is what Applicants claim. And that, not some possible downstream result, is the measure of what must be enabled. What Applicants noted in their Answer, and the Examiner simply failed to respond to, is that the Office has already agreed with Applicants.

In the Office Action dated November 1, 2006 (yes, this case has been in prosecution that long) the Examiner drew restriction between claims of Group V, "drawn to a method of inhibiting HIV viral budding from a host cell" and Claims of Group VI, "drawn to use of a compound capable of binding Tsg101 protein and interfering with the interaction between

Tsg101 and HIV Gag in inhibiting HIV budding, treating HIV infection or preventing AIDS." See, page 3. At page 4, the Action indicates these two classes "are unrelated because they are methods with different modes of operation, with respect to starting materials, physiological mechanisms, protocol procedures, and end products; therefore each method is patentably distinct." In response, Applicants deliberately amended their claims to confine them to a method of inhibiting viral budding. If such claims are in fact patentably distinct from preventing AIDS, and Applicants agree they are, then they should not be measured to the same standard of enablement.

Arguably the most important factor among the eight factors applied in the *Wands* test as enunciated by the Federal Circuit in *In re Wands*, 230 USOUSPQ 546 (BPAI 1986) is "the breadth of the claim." As noted in Appellants' Opening Brief, it is the claim that is the starting and end point for measuring what must be enabled. No part of Appellants' claims call for treating AIDS, treating or preventing HIV, or otherwise providing anti-viral relief. The Examiner offers no rationale for requiring Applicants to prove that which they do not claim. Applicants have demonstrated they can inhibit viral budding from an HIV infected cell. The Patent Office and Examiner Humphries have agreed. They should not be required to prove something they do not claim, something the Patent Office already ruled was a patentably distinct invention.

III. THE ANSWER DOES NOT ADDRESS U.S. PATENT NO. 7,494,767

At pages 16–18 of the Appeal Brief, Applicants discussed at length the consequence of the issuance of parent application as U.S. Patent No. 7,494,767, a United States Patent presumed to be enabling. The Examiner was aware of this argument, see her Answer at page 8, but

fundamentally misunderstands it, arguing, page 11, "a method of identifying inhibitors for the binding of HIV Gag and Tsg101 does not disclose any actual effective peptide inhibitors that can be administered in a method of inhibiting HIV particle generation in cells." Appllants agree that inhibiting binding and inhibiting particle production are methods that are different. But the Examiner has misread the claims of the '767 patent. What is claimed, and presumed enabled (although the presumption of enablement is not confined to the claimed subject matter of an issued U.S. Patent) is a "method for identifying a peptide or fragment…wherein the peptide is effective in reducing HIV particle production."

Thus, the enabling nature of the '767 patent has everything to do with the current claims. Administration of "peptides that reduce HIV particle production…in a mammalian cell culture" which the Examiner concedes are particles that are enabled by the specification will result in reducing HIV particle production in HIV infected cells. Applicants claim no more than this simple result. In Appellants' Brief, the full teaching of the specification as to how to administer the particles was discussed. The Examiner does not appear to find fault with this aspect of the claims or the corresponding specification. Should the Examiner elect to maintain this aspect of the rejection, she is invited to amplify in a supplemental response how it can be that a specification which discloses, in enabling fashion, methods of administering the particles in question to mammalian cells, and which is presumed to enable the identification of PTAP-comprising peptides which reduce particle formation in mammalian cells infected with HIV in a mammalian cell culture, does not enable the administration of just those particles for just that result. In the absence of such, the rejection cannot be sustained, and reversal is respectfully requested.

IV. CONCLUSION

Applicants do not present claims in the case on appeal directed to anti-viral treatment or the inhibition of AIDS. Their claims are directed to administering particles the Examiner has already expressly found the case to be enabling for – PTAP comprising peptides which inhibit binding between Tsg101 and Gag and thereby inhibit viral budding. The presumption of enablement that extends to the '767 reaffirms this enablement – the specification is presumed enabling for the purposes of identifying particles which inhibit viral budding by this binding interference. The specification teaches how to administer these particles. More is not required for enablement.

Reversal of the rejection advanced in this matter is accordingly appropriate, and the same is respectfully requested. An Oral Hearing is requested contemporaneously with the submission of this Reply Brief, 37 C.F.R. §41.47(b), as well as a Petition for extension of time.

Date: May 24, 2010

Respectfully submitted,

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